

Notice of Allowability

Application No.

09/981,684

Applicant(s)

ASCENZI, MARIA-GRAZIA

Examiner

Kandasamy Thangavelu

Art Unit

2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to August 19, 2005.
2. ☒ The allowed claim(s) is/are 1-3 and 10-56.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>August 19, 2005</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>Clean copy of allowed claims.</u> |

DETAILED ACTION

Introduction

1. This communication is in response to the Applicants' communication dated August 19, 2005. Claims 1-3 were amended. Claims 4-9 were deleted. Claims 10-56 were added. Claims 1-3 and 10-56 of the application are pending.

Examiner's Amendment

2. Authorization for this examiner's amendment was given in a telephone conversation by Ms. Dianna Goldenson on November 23, 2005.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to the applicants, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. In the claims:

In amended Claim 1, Lines 9-12, "wherein the second order components are used to determine characteristics of the first order region, and

Art Unit: 2123

wherein a mechanical property of the first order region is determined based on the mechanical properties of the second order components.”

has been changed to

-- wherein a mechanical property of the first hierarchical order region is determined based on the mechanical properties of the second order components.--.

In Claim 10, Lines 1-4, “a third hierarchical order comprising at least one third order component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof corresponding to one or more regions of the second order components, wherein the third order components are used to determine characteristics of the second order components; and”

has been changed to

-- a third hierarchical order comprising at least one third order component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof corresponding to one or more regions of the second order components; and--.

In Claim 15, Lines 3-4, “wherein each subject bone is divided into a plurality of samples from corresponding locations of each subject bone;”

has been changed to

-- wherein a plurality of samples is selected--.

Art Unit: 2123

In Claim 18, Line 4, "each of the samples are subjected to tests to produce data on stress and strain; and"

has been changed to

-- each of the samples is subjected to tests to produce data on stress and strain; and --.

In Claim 28, Lines 2-4, "b) dividing the macroscopic region into a finite number of elements, each element representing an empirically-derived nonhomogeneous second order component comprising one or more osteons, trabeculae, or lamellae;"

has been changed to

-- b) dividing the macroscopic region into a finite number of elements of second hierarchical order, each element representing an empirically-derived nonhomogeneous second order component comprising one or more osteons, trabeculae, or lamellae;--.

In Claim 34, Lines 4-5, "dividing each of the subject bones into a plurality of second order samples, wherein each sample corresponds to a location within the specified macroscopic region of each subject bone;"

has been changed to

-- selecting a plurality of samples --.

A clean copy of the allowed claims is attached.

Reasons for Allowance

4. Claims 1-3 and 10-56 of the application are allowed over prior art of record.

5. The following is an Examiner's statement of reasons for the indication of allowable subject matter:

The closest prior art of record shows:

(1) a method of accounting for the microstructure of the compact bone when determining the overall macroscopic behavior of the bone, using homogenized approximations; compact bone is a heterogeneous medium exhibiting a multiscale composite structure; it is possible to simulate the macroscopic behavior from the microscopic mechanical characteristics using a homogenized approximation; due to the hierarchical structure of the compact bone in three levels, a three level homogenization is used; the model follows two main steps: the first step analyzes the physiological structure of the compact bone using a hierarchical organization; the macroscopic structure is analyzed through the substructures which are further decomposed into further substructures; the mechanical characteristics are then calculated by defining an elasticity tensor for each substructure and computing the overall elasticity tensor from those of the substructure; the analysis assumes the collagen fiber and the hydroxyapatite to be homogeneous (**Crolet**, "Compact bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol 26, No. 6, pp. 677-687, 1993);

(2) application of a two level hierarchical analysis model to predict the anisotropic elasticity of the bone; the bone has a hierarchical structure; on the microstructural level are the

Art Unit: 2123

osteons which are hollow fibers composed of concentric lamellae and pores; at the ultrastructural level, the fibers are a composite of hydroxyapatite and protein collagen; these specific structural features are associated with various physical properties; the model relates the bone stiffness to the orientation of the applied stress with respect to the osteon axis; the hierarchical structure is analyzed using finite element analysis method (**Lakes**, "Materials with Structural hierarchy", *Nature* 361, pp. 511-515, 1993); and

(3) a method of determining the mechanical properties and composition of the cortical bone; the relationship between stresses and strains at a particular point in the bone are governed by the material properties of the local bone; biological processes produce changes in the microstructural and compositional characteristics that affect the mechanical properties of the bone; the classification of the bone tissue as cortical or cancellous is based on the bone porosity; cortical bone is a viscoelastic material; its elastic properties and strength are dependent upon both the rate and duration of the applied loading; the elastic properties and strength are dependent upon the orientation of the bone microstructure with respect to the direction of loading; repeated loading of the cortical bone causes a gradual and progressive loss of bone stiffness (**Carter et al.**, "Clinical orthopedic and Related Research", Number 135, September 1978).

None of these references taken either alone or in combination with the prior art of record discloses a system for modeling macrostructural characteristics of a bone, specifically including:

“a second hierarchical order comprising at least one empirically-derived non-homogeneous second order component representing one or more osteons, trabeculae, or lamellae within the macroscopic region, and

wherein a mechanical property of the first hierarchical order region is determined based on the mechanical properties of the second order components”.

None of these references taken either alone or in combination with the prior art of record discloses a method of producing a model of bone, specifically including:

“dividing the macroscopic region into a finite number of elements of second hierarchical order, each element representing empirically derived non-homogeneous second order component comprising one or more osteons, trabeculae, or lamellae; and

determining a mechanical property of the first order macroscopic region of the selected bone based on the mechanical properties of the second order components”.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance.”

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is

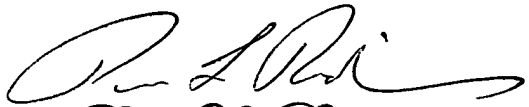
Art Unit: 2123

571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard, can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to TC-2100 Group receptionist: 571-272-2100.

K. Thangavelu
Art Unit 2123
November 26, 2005


Paul L. Rodriguez 11/28/05
Primary Examiner
Art Unit 2125